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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/963,288	11/03/1997	GUNNAR NORSTEDT	10806-48	9881

7590

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EXAMINER

BAKER, ANNE MARIE

ART UNIT

PAPER NUMBER

1632

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Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary	Application No. 08/963,288	Applicant(s) NORSTEDT ET AL.	
	Examiner Anne-Marie Baker, Ph.D.	Art Unit 1632	

All participants (applicant, applicant's representative, PTO personnel):

- (1) Anne-Marie Baker, Ph.D. (3) Clare M. Iery.
 (2) Holly D. Kozlowski. (4) _____

Date of Interview: 15 August 2002.

Type: a) ☒ Telephonic b) ☐ Video Conference
 c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
 If Yes, brief description: _____

Claim(s) discussed: 1, 5, 8, 10, 15, 19, 23, 27, 30 and 44.

Identification of prior art discussed: Lindquester et al. (1989).

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

- i) ☐ It is not necessary for applicant to provide a separate record of the substance of the interview (if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Anne-Marie Baker
 ANNE-MARIE BAKER
 PATENT EXAMINER

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case unless both applicant and examiner agree that the examiner will record same. Where the examiner agrees to record the substance of the interview, or when it is adequately recorded on the Form or in an attachment to the Form, the examiner should check the appropriate box at the bottom of the Form which informs the applicant that the submission of a separate record of the substance of the interview as a supplement to the Form is not required.

It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

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Continuation Sheet (PTO-413)

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

The Attorney submitted proposed claim amendments by facsimile transmission on August 8, 2002.

Discussed all the outstanding rejections in view of the proposed amendments. The Examiner pointed out that the amendment to Claim 8 does not overcome the written description rejection because the specification does not provide support for "an expression vector ... wherein the vector further comprises six enhancer elements, and further wherein each of the enhancer elements comprises the nucleotide sequence TTCTGAGAA". The Attorney pointed to Example 3 for teaching a construct comprising six enhancer elements. However, this example is limited to teaching reporter plasmids comprising six copies of the 52 base pair SPI-GHRE element. There are no teachings in the specification to support expression vectors that comprise other enhancer elements that comprise the nucleotide sequence TTCTGAGAA, as broadly claimed. The claim covers expression vectors that comprise six enhancer elements, where each enhancer element is different from the other five enhancer elements and each enhancer element is of any length, with the only limitation being that it comprises the nucleotide sequence TTCTGAGAA. The specification does not contemplate expression vectors that comprise six enhancer elements, wherein each of the enhancer elements comprises the nucleotide sequence TTCTGAGAA. As support for Claim 8, the Attorney additionally pointed to the abstract for stating that there is "at least one enhancer element comprising the nucleotide sequence TTCTGAGAA upstream of the promoter." However, there is no contemplation of a vector comprising six enhancer elements, wherein each of the enhancer elements comprises the nucleotide sequence TTCTGAGAA. The Attorney indicated that she might amend Claim 8 to limit the enhancer to the nucleotide sequence of SEQ ID NO: 1, unless she can find support in the specification for some alternative claim language. The Examiner reminded the Attorney to point to the support in the specification for any amendment.

Discussed the proposed amendment to Claim 27. The Examiner indicated that she does not find that the proposed amendment would overcome the art rejection because the claimed vector still reads on the art. The composition of the prior art satisfies all the claim limitations as it comprises a structural gene encoding a protein, a promoter, and the enhancer element. The Attorney argued that the presence of the enhancer element in the composition of the prior art is there unintentionally, but that the amendment to the claim specifies that the enhancer element is intentionally added to the gene. The Examiner pointed out that the claim is directed to a composition, and therefore it does not matter how the enhancer element got there, because only the structure of the claimed composition is at issue. The amended clause,

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“wherein the enhancer element is incorporated into the expression vector separately from the structural gene” appears to be a method step, but would not alter the structure of the claimed composition.

Furthermore, the function of the enhancer element is an inherent property of the composition. The Attorney indicated that she would likely amend the claim to recite that the promoter is upstream from the structural gene, and the enhancer element is upstream from the promoter. The Examiner agreed that such an amendment would be helpful, as the arrangement of the elements is critical.

Discussed the proposed amendments to Claim 19. The Examiner pointed out that “the DNA construct” recited in steps (c) and (d) still has ambiguous antecedent basis. Since there is no literal antecedent basis for “the DNA construct” referred to in steps (c) and (d) other than the DNA construct of step (a), the later steps appear to be using the construct that does not comprise the enhancer element. The Examiner suggested that step (a) be amended to recite “a first DNA construct” and step (b) be amended to add the phrase “thereby producing a second DNA construct” and that steps (c) and (d) be amended to recite “the second DNA construct.”

Discussed the proposed amendments to Claim 23. The Examiner does not understand how the enhancer element is “adapted.” The Examiner suggested that the claim language would be clearer if amended to read “when the enhancer element is in a DNA construct incorporated in the genome of a eukaryotic host cell.”